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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/351,985	07/12/1999	FRIEDRICH BRAUN	A32585-PCT-U	1552

21003 7590 10/07/2003

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 10/07/2003

25

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/351,985	Applicant(s) BRAUN ET AL.	
	Examiner Shengjun Wang	Art Unit 1617	

-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of applicants' amendments and remarks submitted July 25, 2003 is acknowledged.

Claim Rejections 35 U.S.C. - 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1–20 are rejected under 35 U.S.C. 103(a) as being unpatentable over both Read et al. (US 5,902,608 of record) and Patat et al. (US 5,589,462 of record) in view of Delmas (US 5,618,663 of record), Dimoudis et al. (US 5,980,888)

3. Read et al. teaches a surgical composition comprising thrombocytes (blood platelet) containing growth factor. The composition is sterile. Deep-freezing and/or lyophilization prepare the thrombocytes. See, particularly, the abstract, the claims and the example 1 on column 5. Note the deep-freezing and /or lyophilization process does not require the addition of albumin. See the claims. Patat et al. teaches a medicinal product for topical application for the promotion of wound healing, which comprising frozen growth factor containing thrombocytes. See, particularly, the abstract, column 1, line 49 bridging column 2, line 7, column 2, line 21 bridging column 3, line14 and column 6,lines 24-31. The freezing temperature is below –15 °C. See, particularly, column 4, lines 31-36. The reference teaches that thrombocytes are known to be one of the principal sources of growth factors. See, column 1, lines 54-64. Growth factors along with other components such as fibronectin, thrombin and collagen are known to be useful for

promoting wound healing. See, particularly, column 1, lines 5-41. The reference teaches that the platelet (thrombocyte) enriched plasma contains about 10^8 to $5x10^8$ thrombocytes. See, column 4, lines 13-29. The reference further teaches that the medicinal product contains other components normally present in a platelet extract, e.g., protein, fibrinogen. See, column 3, lines 6-24.

The primary references do not expressly teach inactivation of viruses with the thrombocytes, or the employment of additional epithelial cells and/or keratinocytes and/or embryonic and/or fetal cells and/or liposomes, and lyophilization of thrombocytes, or particularly recites insoluble thrombocyte fragments.

However, Delmas teaches inactivation of viruses with a thrombocyte product for healing is necessary. See, particularly, column 6, lines 35-46. Dimoudis et al. teach that epithelial cell is known to be useful in wound healing composition. See the title and the abstract.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make a sterile platelet factor enriched thrombocyte compositions with inactivation of viruses and by the addition of other known wound healing components such as epithelial cell.

A person of ordinary skill in the art would have been motivated to make a sterile platelet factor enriched thrombocyte compositions with inactivation of viruses and by the addition of other known wound healing components such as epithelial cell because both using thrombocytes or the growth factor extract from the thrombocytes for wound healing is known. The inactivation of viruses is well known to be necessary for any topical wound healing composition to avoid any possible transmission of disease. The addition of epithelial cells is seen to be obvious since

epithelial cells are known to be useful in would healing composition. The combination of the above known ingredients is seen to be obvious because it is prima facie obvious to combine two or more components each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art; thus, the claimed invention which is a combination of two known germicides sets forth prima facie obvious subject matter. See In re Kerkhoven, 205 USPQ 1069. With regard to the limitation of the presence of a thrombocyte activating stimulus selected from the group consisting of collagen, thrombin, trypsin, ADP, serotonin and andrenalin, note, collagen, thrombin etc. are well known physiological activators which activate platelet to release growth factor. See, column 5, line28-31 in Delmas. Further it is known that exogenous thrombin is known to be useful together with platelet composition and thrombin coagulable protein. Particularly, immediately before the usage, adding thrombin to platelet composition is known. In fact, the feature of the composition disclosed by Patat is that it combines haemostatic and adhesive properties of concentrates of thrombin –coagulable proteins and the platelet extract. See, column 1-3, particularly, column 2, lines 55-59 and column 5, lines 21-30. Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make a composition comprising platelet, thrombin coagulable protein such as fibrinogen, and thrombin for wound healing.

Regarding claim 10, the employment of a composition known to be useful for promoting wound healing for wound healing is seen to be obvious. The optimization of a result effective parameter, e.g., releasing time of active ingredients in a pharmaceutical composition, is

considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215. As to the recitation of "insoluble thrombocyte fragments," note that thrombocyte certainly contains those "thrombocyte fragments" herein defined (see page 4, lines 3-5 in instant specification).

Response to the Arguments

Applicants' amendments and remarks submitted July 25, 2003 have been fully considered, but are not persuasive for reasons discussed below.

Applicants argue that Read does not disclose or suggest the use of thrombocyte fragments or insoluble constituents of thrombocytes. The examiner disagrees. First, as defined in the specification, "thrombocyte fragments" is intended to denote any insoluble thrombocyte constituents that are separable thrombocyte constituents either by filtration including nanofiltration or by centrifugation including ultracentrifugation. Therefore, whole cells of thrombocyte certainly comprise such constituents. Further, the thrombocyte composition of Read is prepared by a serials of cetrifugation and washing (example 1 in column 5), therefore, the thrombocytes obtained therein are expected to have "fragmented thrombocytes" since the cells have been through the centrifugation and washing and the soluble constituents have been removed. Also Patat et al. employ the insoluble part of the thrombocyte (cryoprecipate).

Further, virus inactivation of blood product would be an obvious step for preventing any possible transmission of disease.

For the reasons set forth above, the claims have been properly rejected.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Patent Examiner

SHENGJUN WANG
PATENT EXAMINER

Shengjun Wang

September 28, 2003

RUSSELL TRAVERS
PRIMARY EXAMINER